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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,408	12/12/2003	Richard Storer	06171.105064 IDX 1024	2099

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EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	**PAPER NUMBER**
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,408	STORER ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,23-28,31-44,50,64-68 and 89-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20, 23-28, 31-44, 50, 64-68 and 89-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 5/23/2007 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1-19, 21-22, 29-30, 45-49, 51-63 and 69-88 have been canceled.

2. New Claims 91-92 have been added.

3. Claims 20, 23-24, 31-32, 36 and 64 have been amended.

4. Remarks drawn to rejections under 35 USC 112, first and second paragraphs, double patenting and 103.

Claims 20, 23-28, 31-44, 50, 64-68 and 89-92 are pending in the case.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 20-35 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of ribofuranose from D-fructose, does not reasonably provide enablement for the preparation of a ribofuranose from any cyclic ether, has been overcome by amendment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 20-35 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been overcome by amendment.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of Claims 20-28, 36, 50 and 64-67 provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 10/882,893 ('893 application) is being maintained for reasons of record.

Applicants have requested deferral of this issue until an indication of allowable subject matter in each application. The rejection will be dropped after filing and approval of a Terminal Disclaimer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of Claims 20, 23-28, 31-44, 50, 64-68 and 89-92 under 35 U.S.C. 103(a) as being unpatentable over BeMiller et al (Methods in Carbohydrate Chemistry, 1963, 2, 484-485, IDS document # HK) in combination with The Merck Index (12th edition, 1996, page 275), Sundberg et al (Advanced Organic Chemistry, Part B, 1990, pages 232 and 236), McFarlin (J. Am. Chem. Soc. 1958, 80, 5372-76) and Piccirilli et al (J. Org. Chem. 1999, 64, 747-54; IDS document # HH) is being maintained for reasons of record.

Applicants have traversed the rejection arguing that:

1. BeMiller does not disclose the use of CaO and does not include a step of adding CaO to a solution of fructose as instantly claimed. Merck does not cure this defect. Merck just discloses that calcium hydroxide is formed when CaO is added to water.

2. Sundberg teaches the reduction of a lactone containing compound that is dissimilar to the ribonolactone instantly claimed. McFarlin does not cure this defect.

3. Piccirilli just teaches a tetrabenzoyl substituted ribofuranose and does not render the instant claims obvious in combination with the other references.

4. The examiner fails to provide motivation for combining the cited references.

Applicants' arguments are not found to be persuasive

BeMiller et al teach the conversion of D-fructose (I) to 2-C-methyl-D-ribonolactone (II). The transformation is effected at room temperature using calcium hydroxide (aqueous), carbon dioxide and oxalic acid (pages 284-285, Procedure). The Merck Index teaches that calcium oxide is soluble in water forming calcium hydroxide (page 275, entry # 1733). Hence, one of ordinary skill in the art at the time of the instant invention would readily recognize that reacting CaO with a solution of fructose as instantly claimed as being equivalent to the reaction taught by BeMiller et al. since adding CaO to an aqueous solution of fructose would generate the calcium hydroxide in situ.

Sundberg et al teach the reduction of a lactone carbonyl to the corresponding alcohol using alkoxyaluminohydride reagent (page 236). Even though the reducing agent is not lithiumtri(t-butoxy)aluminum hydride as instantly claimed, one of ordinary skill in the art will recognize that it is structurally very similar and will perform the same reduction as instantly claimed. Sundberg et al also teach (page 232, Table 5.2) that lithiumtri(t-butoxy)aluminum hydride also reduces a carbonyl group to an alcohol.

The selection of a known material based on its suitability for its intended use supports a prima facie obviousness determination. See Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). A long line of cases have held that the mere use of different starting materials, whether novel or known, in a conventional process to produce the product one would expect therefrom does not render the process unobvious. *In re Surrey et al.* (CCPA 1963) 319 F2d 233, 138 USPQ 67; *In re Kanter (CCPA* 1968) 399 F2d 249, 158 USPQ 331; *In re Larsen* (CCPA 1961) 292 F2d 531,130 USPQ 209; *Ex parte Ryland et al* (POBA 1948) 108 USPQ 15. The mere use of different starting materials, whether novel or known, in a

conventional process to produce the product one would expect therefrom does not render the process unobvious. Thus, a process which, from the results obtained, is analogous to a prior art process is not patentable merely because the product thereof is novel and patentable, *Clinical Products, Ltd. V. Brenner, Comr. Pats.* (DCDC 1966) 255 FSupp 155, 149 USPQ 475, or because the applicant discloses a new benefit in addition to those which would be expected to be obtained. Once the general reaction has been shown to be old, the burden is on the applicant to present reason or authority for believing that a group on the starting compound would take part in or affect the basic reaction and thus alter the nature of the product or the operability of the process and thus the unobviousness of the method of producing it, *In re Neugebaueret al* (CCPA 1964) 330 F2d 353, 141 USPQ 205. McFarlin et al teach that lithiumtri(t-butoxy)aluminum hydride is very stable and a mild reducing agent and is soluble in several solvents (page 5372 abstract; page 5373, Table I). One of skill in the art would want to choose the milder lithium tri(t-butoxy)aluminum hydride since it will not cause other side reaction or reductions in addition to reducing the carbonyl group and will also be easier to handle compared to a stronger reducing agent. Solubility in many solvents is an added advantage.

According to Piccirilli ribose sugars have been synthetic targets for decades because of their potential chemotherapeutic value (page 747, Introduction). Piccirilli teaches the use of the benzoyl protected ribose sugars in the synthesis of oligonucleotides. One of skill knows that the benzoyl group is widely used as protecting group in sugar chemistry and would want to extend the carbonyl group reduction to protected ribose sugars.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the prior art and use it in the processes as instantly

claimed since the steps and reagents for the same are seen to be taught in the prior art. As set forth supra, Piccirilli teaches that ribose sugars have been synthetic targets for decades because of their potential chemotherapeutic value. It would have been obvious to one of ordinary skill in the art to react the lactone of BeMiller with a reducing agent in order to produce the desired ribose sugar.

One of ordinary skill in the art would be motivated to use the process of the prior art since the process for the preparation of the lactone and the corresponding alcohol as taught by the prior art involve simple art tested manipulations and the use of mild reducing reagents that would achieve the reduction of the carbonyl group without other side reactions. One of skill in the art would want to reduce the lactone to the corresponding alcohol since it serves as a precursor to making therapeutically useful molecules, as taught by Piccirilli.

It is well within the purview of one of ordinary skill in the art to extend the scope of the process to other solvents and reagents (reducing agents and protecting groups) for the purpose of optimizing the yield of the desired product and the process steps. It is also well known in the art to speed up reactions by using higher temperatures.

Conclusion

Claims 20, 23-28, 31-44, 50, 64-68 and 89-92 are rejected

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

Patrick T. Lewis
Primary Patent Examiner
Art Unit 1623